REMARKS

PENDING CLAIMS AND SUPPORT FOR AMENDMENTS

Upon entry of this amendment, claims 1-13 and 15-21 will be pending in this application. Applicants have amended claim 13 to incorporate claim 14. Applicants have amended claim 18 to correct a typographical error, to remove extraneous language and make the claim more readable, and to clarify that at least part of the inner surface of each housing part is concave.

No new matter has been added.

OBJECTION TO DRAWINGS

At page 2 of the Office action, the Examiner has objected to the drawings as failing to show each feature of the invention specified in the claims. The Examiner has required that the sheath be shown in the drawings, or be deleted from the claims.

Applicants submit herewith proposed drawing corrections, which attempt to illustrate the optional sheath without obscuring the internal features of the prosthesis, the illustration of which appears to Applicants to be more important to ease of understanding the invention than does illustration of an opaque sheath.

Applicants respectfully request approval of the proposed drawing corrections, upon receipt of which Applicants will have corrected formal drawings prepared.

CLAIM OBJECTION

Applicants have corrected the spelling of "viscoelastic" in claim 18.

ANTICIPATION REJECTION OVER SHEPPARD

At pages 2-3 of the Office action, the Examiner has rejected claims 1, 3, 8, and 9 as anticipated under 35 U.S.C. § 102(e) over Shepperd (U.S. Patent No. 4,863,476). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Although the device disclosed in Shepperd may appear to be superficially similar to that recited in the rejected claims, Applicants respectfully submit that the Examiner has overlooked a number of important distinctions between the Shepperd disclosure and the claimed device.

The claims recite the presence of a plurality of resilient, viscoelastic discs dispersed between the upper and lower halves of the cylindrical housing. The Examiner asserts that the cam elements 3 of Shepperd satisfy this requirement. Applicants disagree.

First, Shepperd is silent as to the properties of the cam elements 3 of his device. Thus, there is no explicit disclosure of whether these elements are resilient or viscoelastic. For this reason alone, the Examiner's anticipation rejection is erroneous and should be withdrawn, since anticipation requires that every element or limitation of a claim be disclosed within the four corners of the cited reference.

Second, the function performed by the cam elements of the Shepperd device indicate that resiliency and/or viscoelasticity are not inherent properties of the cams. The Shepperd device is designed to be inserted between adjacent vertebrae in a collapsed state, and then expanded to the appropriate spacing height. This expansion is accomplished by forcing the cam elements to bear against the hard metal parts of the elongate body and force them apart, as illustrated in Figures 1-4 of Shepperd.

Resilient and/or viscoelastic materials would be very bad choices for cam elements that must perform this function, and in fact would likely render the device inoperative, since the cams would deform rather than force the parts of the elongate body apart to the desired height.

Another function performed by the cam elements of the Shepperd device, as illustrated in Figure 5, is to provide a pivot point around which the parts of the elongate body can rock. Resilient and/or viscoelastic materials would again provide a poor choice, since they would deform rather than provide a stable, hard rocking surface as required by Sheppard.

Because the cam elements of Shepperd are not disclosed to be resilient, viscoelastic discs, either explicitly or inherently, the Examiner has failed to cite a reference that contains this element of the claims, and his anticipation rejection is erroneous and should be withdrawn.

ANTICIPATION REJECTION OVER ROGOZINSKI

At page 3 of the Office action, the Examiner has rejected claims 11-13, 16, and 17 under 35 U.S.C. § 102(e) over Rogozinski (U.S. Patent No. 5,888,226). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

As in the case of the anticipation rejection over Shepperd, the Examiner has apparently overlooked at least one significant distinction between the claimed device and the disclosure of Rogozinski. Claims 11 and 12 recite a hollow cylindrical housing. In other words, the claims recite that the housing is shaped like a hollow cylinder. Nowhere in Rogozinski is such a shape suggested. To the contrary, both

the cross-sectional diagrams of Figure 9 and of Figures 10-12 show configurations that are not even remotely cylindrical.

Claim 13 has been amended to incorporate the limitations of claim 14, which was not subject to this rejection.

Claims 16 and 17 recite that a viscoelastic prosthetic disc having viscoelastic properties (claim 16) and having a soft and resilient interior (claim 17). The main body 10 of the prosthetic disc of Rogozinski is composed of a substantially rigid and durable biocompatible material. Rogozinski does not teach that his prosthetic disc have viscoelastic properties, as recited in claim 16, or that the disc 10 have a soft, resilient interior, as recited in claim 17. To the contrary, Rogozinski teaches that disc 10 should be substantially rigid, rather than resilient or viscoelastic.

Because each of the rejected claims differs significantly from the device disclosed in Rogozinski, as described above, there is no anticipation, and the Examiner's rejection should be withdrawn.

ANTICIPATION REJECTION OVER CAUTHEN

At page 3 of the Office action, the Examiner has rejected claims 18 and 19 under 35 U.S.C. § 102(e) over Cauthen (U.S. Patent No. 6,179,874). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Cauthen discloses, in Figure 5, an embodiment of intervertebral implant having elements with concave and convex inner surfaces, and describe a bowl shaped cap that fits between the mating concave and convex surfaces. By contrast, claims 18 and 19 make clear that both inner surfaces of the housing must contain at least some

concavity. This is not disclosed in the embodiment of Cauthen relied upon by the Examiner. Accordingly, Cauthen does not anticipate the claimed invention.

OBVIOUSNESS REJECTION OVER SHEPPERD IN VIEW OF CAUTHEN

At page 4 of the Office action, the Examiner has rejected claims 4-6 and 10 under 35 U.S.C. § 103(a) as obvious over Shepperd in view of Cauthen. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

The Examiner apparently recognizes that Shepperd fails to disclose a threaded exterior surface or recesses to permit bone ingrowth, and in an attempt to cure this deficiency relies upon Cauthen, asserting that it would have been obvious to modify the exterior surface of the Shepperd device with threads and recesses.

First, even assuming that one of ordinary skill in the art would have been motivated to combine the teachings of Shepperd with those of Cauthen and put threads or recesses on the exterior surface of the Shepperd device, the resulting device still does not fall within the scope of the claims, because Cauthen does not cure the deficiencies of Shepperd described above with respect to the anticipation rejection of claim 1.

However, one of ordinary skill in the art would not have been motivated to thread the exterior surface of the Shepperd device. The Shepperd device is designed to slide into a prepared cavity and then expanded to its desired height. The outer surface is porous, permitting bone ingrowth. *See* Shepperd, column 2, lines 45-48. The Cauthen device, by contrast, is already at its desired height when inserted, and is designed to be inserted by screwing it into the cavity, so that the threads on the device

cut corresponding threads into the bone. These threads help pull the device into the intervertebral space and direct bone fragments to fusion chambers in the outer surface of the device. *See* Cauthen at column 7, lines 18-30.

Because of these fundamental differences in the techniques for insertion of the device, and because these insertion techniques dictate, to a large extent, the form of the outer surface of the device, a worker of ordinary skill in this art would not have been motivated to look to Cauthen and apply the threaded and/or fusion chamber-containing surfaces disclosed therein to the Shepperd device. As a result, the Examiner has failed to establish a prima facie case of obviousness, and the rejection should be withdrawn.

OBVIOUSNESS REJECTION OVER SHEPPERD

At page 4 of the Office action, the Examiner has rejected claims 2 and 7 under 35 U.S.C. § 103(a) as obvious over Shepperd. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

First, the Examiner has provided no motivation for one of ordinary skill in this art to modify the device taught in Shepperd to contain all of the limitations recited in claim 1, as described in detail above with respect to the anticipation rejection over Shepperd.

Second, the Examiner has provided absolutely no motivation for modifying the Shepperd device to contain the features recited in claims 2 and 7, aside from the stereotypical "obvious matter of design choice" arguments, together with an attempt to shift the burden to Applicants of establishing the importance of the design choice.

In effect, the Examiner has engaged in a clear hindsight reconstruction of the claimed invention without even a reference to support his position.

If the Examiner is relying upon some theory of "common knowledge" or "well known" prior art, then Applicants challenge the Examiner to provide a reference showing that this knowledge is common, or to cite the alleged well-known art. See MPEP § 2144.03. If the Examiner is relying upon personal knowledge, Applicants request that the Examiner provide an affidavit or declaration under 37 C.F.R. § 104(d) setting forth the details and basis for this knowledge. If the Examiner is relying upon some theory that the differences are "aesthetic design changes" under MPEP § 2144.04, then the Examiner is requested to explain how the differences do not effect the function of the device.

With respect to claim 2, Shepperd actually teaches away from modifying the cams to have an ovoid shape. As described above, the cams operate to force apart the elongate body portions of Shepperd, and to hold these elongate body portions apart at the appropriate height. Because the inner surfaces of the Shepperd elongate body portions are essentially planar, the upper and lower surfaces of the cams must also be planar in order to allow them to move into the proper position for holding the body portions apart (by sliding of the cams along the inner surfaces of the body portions). An ovoid shaped cam would not perform this function as well as a cam with flat surfaces, so that one of ordinary skill in this art would not have been motivated by "obvious design choices" to substitute an ovoid design for the non-ovoid design described in Shepperd.

Since the Examiner has failed to establish a prima facie case of obviousness, this rejection should be withdrawn.

OBVIOUSNESS REJECTION OVER ROGOZINSKI

At page 5 of the Office action, the Examiner has rejected claims 14 and 15 under 35 U.S.C. § 103(a) as obvious over Rogozinski. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Claim 14 has been canceled by the present amendment and incorporated into claim 13. The Examiner apparently concedes that Rogozinski completely fails to teach or suggest a threaded surface or external recesses, but nevertheless asserts that such modifications would have been obvious because "it is common knowledge in the prior art to have threaded external surfaces and a plurality of recesses in the same field of endeavor for the purpose of attaching the device within the vertebrae plates."

The standard for determining whether a claim is obvious is not whether the individual elements of the claim are "common knowledge," but whether one of ordinary skill in the art would have been motivated to modify the cited art in such a way as to eliminate the differences between the disclosure in the art and the claimed invention. It is largely irrelevant, and an incomplete rationale, to assert that it would have been obvious to modify a specific reference teaching based on "common knowledge" without any explanation of why a worker of ordinary skill in the art would have been motivated to make the modification.

The device described in Rogozinski is not disclosed to be suitable for implantation by screwing into a prepared cavity. This is not surprising, since neither of the embodiments disclosed by Rogozinski have outer surfaces shaped such that

threading is reasonable or even possible. To the contrary, Rogozinski discloses that the prosthesis disclosed therein is held in place by the concave endplates of the adjoining vertebral bodies, which contact the convex surfaces of the prosthesis. See column 2, lines 4-23. In situations where the endplates are damaged or diseased, one or more vertebral attachment members can be used. The attachment members can be affixed to the vertebrae, but the manner of affixation clearly does not contemplate or suggest screwing a threaded prosthesis into the bone, since only one attachment member need be present if only one endplate is damaged. Without two attachment members, a continuous thread cannot be formed. See column 2, lines 40-60.

Accordingly, there is no need for a threaded implant surface, because the implant is not designed to be screwed into the bone, but rather is designed to conform to the shape of the vertebral endplates, and to be held in place by them, without the need for threads. One of ordinary skill in this art would therefore not have been motivated to add threads to the device of Rogozinski. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness, and the rejection should be withdrawn.

OBVIOUSNESS REJECTION OVER CAUTHEN

At pages 5 and 6 of the Office action, the Examiner has rejected claims 20 and 21 under 35 U.S.C. § 103(a) as obvious over Cauthen. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

First, Cauthen does not teach or suggest the elements of claim 18, from which claims 20 and 21 depend, as explained above with respect to the Examiner's

anticipation rejection. Thus, even if it were obvious to modify Cauthen in the manner suggested by the Examiner, the claimed invention would not be obtained.

Second, the Examiner admits that Cauthen is silent with respect to the presence of a sheath or the use of a plurality of nuclei. However, the Examiner disregards these deficiencies without any explanation as to motivation (other than to reiterate the hindsight result from making the modification). The Examiner then concludes that these differences would nevertheless have been obvious to one of ordinary skill in the art. Applicants respectfully submit that the Examiner has engaged in impermissible hindsight in reaching this conclusion, and that the cited references fail to suggest modifying Cauthen in the manner suggested. Certainly, Cauthen does not suggest using a sheath to promote growth of bone tissue into the implant (sheaths generally are used to provide complete encapsulation of the interior of the implant, not to promote bony ingrowth), or using different sized nuclei to obtain different sized implants (Cauthen discloses only a cap, without reference to the significance of its size).

For at least these reasons, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness, and his rejection should be withdrawn.

Applicants respectfully submit that the claimed invention is novel and not obvious over the cited references, and that this application is in condition for immediate allowance. An early notification to that effect is earnestly solicited.

MARKED UP COPY OF AMENDED CLAIMS

~~13~~ (Amended) A plurality of disc prostheses located within a human spine, each prosthesis comprising an upper half housing engaging a cephalad bone inferior end plate; a lower half housing engaging a caudal vertebral bone superior end plate; and at least one resilient disc interposed between each of the housing halves, wherein each prosthesis has a threaded exterior surface.

~~15.~~ (Amended) A plurality of disc prostheses according to claim [14] 13, wherein each prosthesis has recesses defined in its exterior surface to permit bone ingrowth.

~~18.~~ (Amended) A disc prosthesis comprising:[, in combination,]

a housing, [the housing having] comprising at least two rigid, confronting and complimentary parts, each having an exterior surface together defining a general continuous thread formation, and each having an interior surface at least a portion of which is concave; [the housing including at least two rigid, confronting and complimentary parts, the prosthesis further comprising]

at least one resilient, [viscoelectric] viscoelastic disc interposed between the housing parts to maintain the housing parts separate from one another but to provide cushioning between the housing parts and to permit limited motion [from between] of the housing parts.

The Commissioner is hereby authorized to charge any deficiencies or credit any overpayment to Deposit Order Account No. 11-0855.

Respectfully submitted,

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